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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,661	ZHANG ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-7, 9-14, 16, 18-25* is/are pending in the application.

4a) Of the above claim(s) *6,14,16,18 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,9-13 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1, 3-5, 7, 9-13 and 19-21, to the extent they read on plants) in the reply filed on 11 August 2004 is acknowledged.

The traversal is on the ground(s) that the claim has been amended so that the DNA of Group I encodes the protein of Group III. This is not found persuasive because not all DNAs of claim 1 encode proteins. Claim 1 is drawn to any nucleic acid that hybridizes under moderate stringency conditions to SEQ ID NO:1; not all such nucleic acids will encode proteins. Thus, the groups are not coextensive.

The traversal is on the ground(s) that all five groups form a single general inventive concept, the special technical feature of SEQ ID NO:1 and 2, which is shared by all groups. This is not found persuasive because under lack of unity rules, Applicant is entitled to examination of one product, one method of using it and one method of making it. Group I is drawn to a product (a nucleic acid), a method of using it (a method for increasing disease resistance in a plant by transformation), and a method of making it (a method of isolating the nucleic acid). Group II is a second method of using the nucleic acid of Group I, and Group V is a third method for using the nucleic acid of Group I. Group III is a second product (a protein) and a method of using it; Group IV is a second method of using the product of Group III.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 14, 16, 18 and 22-25 are withdrawn from consideration as being drawn to nonelected inventions. Claims 1, 3-5, 7, 9-13 and 19-21 and examined to the extent they read on plants.

2. The abstract is not descriptive of the instant invention, which is XXXXXXXXXXXXX. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

3. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-5, 7, 9-13 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of nucleic acids that hybridize to SEQ ID NO:1 or to any nucleic acid that encodes SEQ ID NO:2. In contrast, the specification only describes a coding sequence from a Bacillus species that comprises SEQ ID NO:1. Applicant does not describe other nucleic acids encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Additionally, no description is provided as to the function of the nucleic acid in claim 1, part (c).

The specification also fails describe signal peptide coding regions and membrane-attachment coding regions.

Lastly, the donor organisms required by the method of claims 19-21 are not described; therefore, the claimed invention lacks an adequate written description.

Hence, Applicant has not, in fact, described nucleic acids that that hybridize to SEQ ID NO:1 or to any nucleic acid that encodes SEQ ID NO:2, and constructs comprising them, within the full scope of the claims. Because the starting materials are not described, the methods are likewise not described. Thus, the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions and methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

6. Claims 1, 3-5, 7, 9-13, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2, vectors comprising them, cells transformed with the vector and a method of using the nucleic acids to increase disease resistance in a plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2, vectors comprising them, cells transformed with the vector and a method of using the nucleic acids to increase disease resistance in a plant.

The instant specification, however, only provides guidance for isolation of SEQ ID NO:1, which encodes SEQ ID NO:2, from bacterial isolate 240B1 (pg 12-17); and expression in *Erwinia carotovora* to produce a strain with decreased virulence on plants (pg 17-18).

The instant specification fails to provide guidance for nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2, vectors comprising them, cells transformed with the vector and a method of using the nucleic acids to increase disease resistance in a plant.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain lactonase activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making "conservative" substitutions (*e.g.*, substituting one polar amino acid for another, or one acidic one for another) does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines

that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). All these mutated proteins, however, would have at least 95% identity to the original protein. The nucleic acids encoding all these mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2. Making all possible single amino acid substitutions in an 250 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19^{250} nucleic acids. Because nucleic acids that hybridize to SEQ ID NO:1 or that hybridize to any nucleic acid that encodes SEQ ID NO:2 would encode proteins with many amino acid substitutions, many more than 19^{250} nucleic acids would need to be made and analyzed.

Molina et al (2003, FEMS Microbiol. Ecol. 45:71-81) teach that application of lactonase-expressing bacterial strains eliminated the effectiveness of disease-suppressing bacteria, resulting in diseased plants (paragraph spanning the columns, pg 78). Zhang (2003, Trends Plant Sci. 8:238-244) teach that transformation of plants with another nucleic acid that encodes an enzyme that controls lactone levels resulted in disease resistant plants in one case, but more susceptible plants in the other, and suggest that these results mean fine-tuning is required to match host-pathogen combinations (paragraph spanning the columns, pg 242).

The specification does not teach under which promoters the nucleic acid that hybridizes to SEQ ID NO:1 or that hybridizes to any nucleic acid that encodes SEQ ID NO:2 must be expressed from in plants to provide disease resistance.

As the specification does not describe the transformation of any plant with a nucleic acid that hybridizes to SEQ ID NO:1 or that hybridizes to any nucleic acid that encodes SEQ ID NO:2, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with increased disease resistance, if such plants are even obtainable.

The specification does not teach from which organisms the nucleic acid of claim 1, part (c) can be isolated, or which organisms can be used as donor organisms in the method of claims 19-21. Additionally, as bacterial isolate 240B1 is not deposited or publicly available, it cannot even be used to isolate the nucleic acid of SEQ ID NO:1.

As the specification does not describe the isolation of a nucleic acid that hybridizes to SEQ ID NO:1 or that hybridizes to any nucleic acid that encodes SEQ ID NO:2 from a publicly available donor organism, undue trial and error experimentation would be required to screen through the myriad of donor organism s encompassed by the claims to identify those that have a nucleic acid that hybridizes to SEQ ID NO:1 or that hybridizes to any nucleic acid that encodes SEQ ID NO:2, if such donor organisms are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-5 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "the coding portion of SEQ ID NO:1" in part (a). Any nucleic acid has at least 6 potential reading frames, and thus at least 6 coding portions. It is unclear to which the claim refers.

9. Claims 1, 3-5, 7, 9-13 and 19-21 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid that hybridizes under the conditions specified in claim 1, part (c) to SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2. The closest prior art is SEQ ID NO:13 from US Patent 5,993,827, which has 48% identity to SEQ ID NO:1.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
October 28, 2004

ANNE KUBELIK
PATENT EXAMINER